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| **California Medical Board Guidelines for Prescribing Controlled Substances for Pain, 2010**  **(this is directly quoted from their document)** | **Contra Costa Regional Medical Center Annotations, 2011**  **(suggestions researched by CCRMC staff)** | **References** |
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| Source: Medical Board of California. Guide to the laws governing the practice of medicine by physicians and surgeons. 6th edition, 2010, pages 53-59. | Source: specifics for chronic pain management in outpatient setting selected from clinical practice guidelines and experience (compiled by Wadle with input from other CCRMC and Health Center providers) |  |
| *(Due to its source, language in this section is specific to physicians/surgeons though content applies to nurse practitioners as well)* | Refer to *Contra Costa Regional Medical Center and Health Centers,* Nurse Practitioner Standardized Procedure, Revised April 2010 | Business and Professions Code of California, Chapter 6. Nursing, Article 9. Clinical Nurse Specialist, 2836.1 – 2836.3 |
| ***History/Physical Examination*** |  |  |
| A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance. | Use numerical scale (0-10) to document level of pain. |  |
|  | Document ability to perform Activies of Daily Living, Independent Activies of Daily Living, care for home/family, work, etc. (appendix 1) | Chou, et al |
|  | Use a tool to evaulate risk of opioids and to assist in determining whether chronic opioid treatment is appropriate or not. (appendix 2) | Chou, et al |
|  | Remember alcohol use with opioids increases the risk of both. |  |
|  | Patient activity report (PAR) from the Department of Justice is a useful part of the history. Baseline and periodic reports are strongly recommended. (appendix 3) |  |
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| ***Treatment Plan, Objectives*** |  |  |
| The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment. | Include trial of non-medication treatments (exercise, TENS, Pain & Wellness Group, etc.)  Include trial of trial of non-opioid medication treatments. Acetaminophen and/or NSAIDs may help musculoskeletal complaints. TCAs and anticonvulsants may help neuropathic pain particularly and chronic pain in general. Tramadol is also a non-opioid option, though cases of addiction have occurred.  Consider initiation of opioids a trial of treatment and have a plan for criteria for defining success or failure. Stop opioid treatment early if goals are not achieved. | Chou, et al |
| Annotation One: Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan. | Address sleep, which is always disrupted by chronic pain. Be wary of benzodiazepines, which generally do not improve restful sleep quality, are highly addictive, and increase the risks of opioid overdose. | Washington State |
| Treating anxiety/depression may improve pain and does improve ability to live with and manage chronic pain in many even if initial symptoms are not severe | Washington State |
| Urine toxicologies are recommended at least once a year for all and more frequently for high risk patients (appendix 4) | Chou, et al |
|  | Consider long acting opioids for patients with chronic, daily pain on 60 mg morphine equivalent per day. If pain is very specifically activity related, short acting opioids may be appropriate. Long acting opioids should never be prescribed “prn.” |  |
| Annotation Two: When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision. | Methadone has an extremely long half life, variable dose conversion from other opioids, ability to cause QTc prolongation and has the highest per user rate of unintentional overdose death. It should only be used in carefully selected patients by clinicians with proper knowledge and experience. It is not a first line drug. When used, an EKG prior to initiation and when at full dose is recommended with particular caution if QTc is over 450 and discontinuation if over 500. In addition, dosing must begin low with increases no faster than after 5 days. (appendix 5) |  |
|  | While there is no theoretical upper limit for opioid dosing, people unresponsive to morphine equivalent 300 mg/day, methadone 120 mg/day, or fentanyl 100 mcg patch likely have pain that is not opioid responsive and generally should not have their doses increased without consultation/second opinion. | Chou, et al |
|  | morphine equivalent dose calculator http://www.agencymeddirectors.wa.gov/Files/DosingCalc.xls | Washington State |
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| ***Informed Consent*** | Make a written agreement; ours is the Chronic Pain Medicine Agreement form MR 446 and can also be dictated under work type 44. | Chou, et al; Federation of State Medical Boards; |
| The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian. | Known complications of chronic opioid treatment include constipation, ileus, nausea, puritis, fatigue, cognitive slowing, habituation, increased sensitivity to pain, hypogonadism, and sleep apnea, and overdose. Overdose prevention education is particularly important with long acting opioids. | Chou, et al; Federation of State Medical Boards |
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| ***Periodic Review*** |  |  |
| The physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. | For high risk patients provider contact weekly to every 3 months is reasonable depending on the most recent behaviors. Remember any history of alcohol or other drug misuse, co-occurring major mental health disorders, and aberrant behaviors make someone high risk. Anyone on over morphine equivalent 200 mg/day, methadone 80 mg/day, or a fentanyl 75 mcg patch should be considered high risk. | Chou, et al suggest up to weekly in high risk  Washington State suggests morphine equivalent of 120 mg/day as max dose |
| Annotation One: Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. | For low risk patients on low risk doses (on low dose short acting opioid), provider contact every 6 months after a stable plan is developed and being followed without difficulty is reasonable. | Chou, et al suggests 3 to 6 months. |
| Annotation Two: Satisfactory response to treatment may be indicated by the patient’s decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient’s response to treatment. | There are times opioid prescribing should stop, such as when active addiction or diversion is occurring. In cases of active addiction, opioids prescribed for pain can be tapered off. (appendix 6) | Chou, et al; Federation of State Medical Boards; Washington State |
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| ***Consultation*** |  |  |
| The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist. | Since this is very difficult to obtain pain medicine or addictionology consults within our system at the time of this writing (2011), these patients may not be appropriate candidates for chronic opioid therapy in the ambulatory clinic setting. | Chou, et al; Federation of State Medical Boards; Washington State |
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| ***Records*** |  |  |
| The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan. | Document chronic pain and location on data base.  Document pharmacy of choice for filling controlled substance prescriptions. |  |
|  | Document long range plan for opioid dosing so it is clear to colleagues cross covering. |  |
|  | Document phone conversations, missed visits, contacts from pharmacies, family members and other providers. |  |
| Annotation One: Documentation of periodic reviews should be done at least annually or more frequently as warranted. |  |  |
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| ***Compliance with Controlled Substances Laws and Regulations*** | In general, do not treat active addicts with controlled substances for chronic conditions. The potential for misuse, diversion, and overdose are much higher in active addicts and we are required to prescribe only when we are reasonably certain that what we prescribe is being used by the person we prescribe it to for the intended therapeutic purpose. See postscript below. | Federation of State Medical Boards;  Gourlay & Heit, 2005; Federal Controlled Substances Act |
| To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions.  Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions. | Do not post date prescriptions. You may prescribe up to 90 days supply of controlled substances at one time by writing multiple separate controlled substance scripts dated the date written and noted “to be filled on XXXX.” | Federal Drug Enforcement Agency Policy |
|  | Do not transfer patients from methadone maintenance treatment to yourself for treatment of pain and addiction unless you have consulted with the methadone treatment facility and clinician there agrees it is appropriate (it is illegal to provide addicts opioids for treatment of addiction outside of a licensed addiction treatment facility.) |  |
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| ***Postscript*** |  |  |
| While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain, there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (Sections 11215-11222 CALIFORNIA HEALTH AND SAFETY CODE). The California Intractable Pain Treatment Act (CIPTA) does not apply to those persons being treated by the physician and surgeon only for chemical dependency because of use of drugs or controlled substances (Section 2241.5(d)). The CIPTA does not authorize a physician and surgeon to prescribe, dispense, or administer controlled substances to a person the practitioner knows to be using the prescribed drugs or controlled substances for non-therapeutic purposes (Section 2241.5(e)). |  |  |
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Appendix 1

Activities of Daily Living/Instrumental Activities of Daily Living

Activities of Daily Living

Bathing

Dressing

Grooming

Mouth Care

Toileting

Walking

Taking stairs

Eating

Transferring bed/chair

Instrumental Activities of Daily Living

Shopping

Cooking

Managing Medications

Using the telephone/finding phone numbers

Housework

Laundry

Driving or taking public transportation

Managing finances

Appendix 2

See separate attachments (available on iSite only) of tools to evaluate risks of opioids.

These include:

The Opiod Risk Tool (ORT)

DIRE Score: Patient Selection for Chronic Opioid Analgesia

(Diagnosis, Intractability, Risk, Efficacy)

CAGE-AID Questionnaire

(Cut down, Annoyed, Guilty, Eye-Opener)

Appendix 3

Patient Activity Report

The California Prescription Drug Monitoring Program is called CURES. It is designed to recognize and minimize abuse and diversion of prescription medications by providing access to records of prescriptions filled for controlled substances, or patient activity reports.

Prescribers must register electronically to use the system, and can do so at the link below.

<https://pmp.doj.ca.gov/pmpreg/>

Appendix 4

Urine Toxicology Screens

(created by Dawn Marie Wadle, MD)

The current send out test used at CCRMC & HC:

Has potential false positives for amphetamines. To confirm a positive is methamphetamine, you must order a GCMS by calling the lab and asking to have it added to the test after you aware it is positive.

Does not reliably detect oxycodone. You can order an ELIZA for oxycodone, which is code 4422U for our outside toxicology lab, and this has a 100 ngm cut off level and should detect people taking regularly doses. A GCMS is required if you wish to be absolutely certain someone is or is not taking it.

Does not detect fentanyl.

Does not reliably detect clonazepam, though does detect other benzodiazepines

Appendix 5

Methadone

(Summary by Dawn Marie Wadle, MD)

Methadone is extremely long acting (elimination half life varies from 5 to 130 hours, mean 22)

There is a 17 fold variation in interindividual methadone blood levels for a given dose due to variations in cytochrome P450 pathway metabolism.

Methadone metabolism is impacted by a long list of other medications.

Use of benzodiazepines and other sedatives with methadone has proven particularly dangerous.

Methadone is associated with QT prolongation.

Dose equivalencies are notoriously unreliable.

Accidental overdose deaths involving methadone have increased 5 fold in the past decade and involve both those to whom it has been prescribed and others. We have had such deaths, along with non-fatal overdoses, among patients at CCRMC & HC.

When prescribing methadone:

Get baseline EKG, and when at final dose or sooner prn

Carefully instruct patients regarding the slow onset of pain relief and the importance of not increasing their own dose or taking extra pills early because they’re not immediate benefit. Warn patients that doing so could cause death.

Remind patients not to share their medications with anyone else, as it is both illegal and extremely dangerous.

Begin dosing at 5 mg BID in those not on long acting opioids, or the lowest estimate of dose equivalency calculations for those already on long acting opioids.

Wait a week between dose changes.

Methadone comes in 5 and 10 mg pills. 2.5 mg is the lowest dosing increment reasonable with pills. Liquid (10 mg/ml) is available though rarely stocked by pharmacies.

Never prescribe prn dosing.

Be aware of all possible medication interactions.

Do not start new sedatives and methadone simultaneously.

Be extremely cautious if prescribing sedatives and methadone concomitantly, even if one or the other is a long term medication.

Appendix 6

Weaning Opioids

Excerpted from Chou, R, et al. Opioid Treatment Guidelines: Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. The Journal of Pain, Vol 10, No 2 (February), 2009: pp 120-121

“Approaches to weaning range from a slow 10% dose reduction per week to a more rapid 25% to 50% reduction every few days. Evidence to guide specific recommendations on the rate of reduction is lacking, though a slower rate may help reduce the unpleasant symptoms of opioid withdrawal. Factors that may influence the rate of reduction include the reason driving the decision to discontinue [chronic opioid therapy], presence of medical and psychiatric comorbidities, the starting dose, and the occurrence of withdrawal symptoms as the process is initiated. Anecdotal clinical experience of panel members suggests that at high doses (eg, over 200 mg/d of morphine or equivalent), the initial wean can be more rapid. The rate of dose reduction often must be slowed when relatively low daily doses, such as 60 to 80 mg daily of morphine

(or equivalent), are reached, due to occurrence of more withdrawal symptoms. Patients weaned from [chronic opioid therapy] because of lack of effectiveness may report improvements in well-being and function without any worsening in pain, though other patients may experience pain hypersensitivity during opioid withdrawal. Clinicians

should continue to treat patients who are withdrawn from [chronic opioid therapy] for their painful condition as well as for substance use or psychiatric disorders.”

Appendix 7

References

Chou, R, et al. Opioid Treatment Guidelines: Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130

*The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc.,* Model Policy for the Use of Controlled Substances for the Treatment of Pain Federation of State Medical Boards of the United States, Inc**.**  *May 2004*

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Washington State Agency Medical Directors’ Group. Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: *an educational pilot to improve care and safety with opioid treatment* March 2007